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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/839,136 | 04/23/2001 | Naoyuki Taniguchi | 02356/7 | 2908 |

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| EXAMINER |
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RAO, MANJUNATH N

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| ART UNIT | PAPER NUMBER |
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1652

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/839,136 | TANIGUCHI ET AL. | |
| | Examiner | Art Unit | |
| | Manjunath N. Rao, Ph.D. | 1652 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-37 is/are pending in the application.
- 4a) Of the above claim(s) 30-34, 36 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 29-37 are currently pending and are present for examination. Claims 29 and 35 are now under consideration. Claims 30-34, 36-37 remain withdrawn from consideration as being drawn to non-elected subject matter.

Examiner acknowledges applicants' corrected sequence information. Applicants' amendments and arguments filed on 10-30-03, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). Contrary to applicants assertion that an English translation was filed as an attachment in the above mentioned response, such an attachment was not received by the Office. Examiner urges applicants to provide a copy of the English language translation in order to perfect the foreign priority date.

Claim Objections

Claim 29 is objected to because of the following informalities: Claim 29 fails to provide the "α" or "β" status of the linkages in the acceptor/product molecule (see lines 4-7). Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 29, 35 are rejected under 35 U.S.C. 102(a) as being anticipated by Uozumi(a) et al. (J. Biol. Chem., Nov. 1996, Vol. 271(44):27810-27817 recited in IDS). This rejection is based upon the public availability of a printed publication and as the invention was known or used by others in this country, or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent. Claims 29, 35 of the instant application are drawn to a recombinant porcine α 1,6-fucosyltransferase capable of transferring fucose from GDP-fucose to hydroxy group at position 6 of N-acetylglucosamine, has an optimum pH of about pH 7.0, can retain activity after 5 hours of treatment at 4° C a pH range of 4.0-10.0, has an optimum temperature of about 30-37° C and has no requirement for divalent metal ions and is not inhibited in the presence of 5 mM EDTA and has a molecular weight of about 60,000 and is purified from porcine source, and a recombinantly produced said enzyme wherein the recombinant enzyme is produced by culturing a transformant transformed with a vector comprising the polynucleotide with SEQ ID NO:1 or a polynucleotide encoding the amino acid sequence SEQ ID NO:2 followed by harvesting the expressed enzyme. Uozumi et al. disclose a α 1,6-fucosyltransferase isolated from pig brain (see sequence alignment, with Accession No. P79282 provided in the previous Office action) as the enzyme having 100%

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sequence match with SEQ ID NO:2. The reference also discloses the recombinant form of the enzyme produced by culturing a transformant transformed with a vector comprising the polynucleotide encoding the amino acid sequence, SEQ ID NO:2, followed by harvesting the expressed enzyme. Therefore, Uozumi et al. anticipate claims 29, 35 of this application as written.

In response to the above rejection in the previous Office action, applicants have traversed the rejection arguing that as the instant application has foreign priority date that is earlier to the reference date, said reference does not anticipate. Applicants also submit that they have perfected their foreign priority date by providing English translation of the Japanese priority document. However, as such an English was not received by the Office, Examiner continues to maintain the above rejection.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 29 and 35 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Uozumi(b) et al. (Biochemistry, 1995, Vol. 67(7):abstr. no.4053, recited in the IDS), and the common knowledge in the art of molecular biology (provided by several Molecular biology laboratory manuals, for example Maniatis et al., 1989). Claims 29 and 35 are drawn to a recombinant porcine α 1,6-fucosyltransferase capable of transferring fucose from GDP-fucose to hydroxy group at position 6 of N-acetylglucosamine, has an optimum pH of about pH 7.0, can retain activity after 5 hours of treatment at 4° C a pH range of 4.0-10.0, has an optimum temperature of about 30-37° C and has no requirement for divalent metal ions and is not inhibited in the presence of 5 mM EDTA and has a molecular weight of about 60,000 and a recombinantly produced said enzyme wherein the recombinant enzyme is produced by culturing a transformant transformed with a vector comprising the polynucleotide with SEQ ID NO:1 or a polynucleotide encoding the amino acid sequence SEQ ID NO:2 followed by harvesting the expressed enzyme. Uozumi et al. disclose a α 1,6-fucosyltransferase isolated from pig brain which is non-recombinant and exhibits almost all of the characteristics as claimed in the instant claims. The enzyme disclosed by Uozumi et al. exhibits the same product formation, has a molecular weight of about 60,000, an optimal pH of about 7.0 and requires no divalent ions for activity and is not inhibited by 5mM EDTA. The reference does not disclose the amino acid sequence, optimum temperature or the pH stability. However, based on all other characteristics Examiner takes the position that characteristics such as amino acid sequence, optimum temperature and pH stability are inherent characteristics of said enzyme even though such characteristics have not been disclosed in the reference (Since the Office does not have the facilities for examining and comparing applicants' protein with the protein of the prior art, the

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burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594). Furthermore as applicants have not shown any structural or functional difference between the purified and recombinant enzyme, the purified enzyme of the reference reads on the recombinant enzyme and therefore is anticipated by Uozumi et al. Therefore, Uozumi et al. anticipate claims 29, 35 of this application as written.

Or in the alternative, the reference of Uozumi et al. and the common knowledge in the art of making recombinant proteins renders the above invention *prima facie* obvious to those skilled in the art. The reference of Uozumi et al. discloses the isolation, purification and characterization of porcine α 1,6-fucosyltransferase from a porcine source (non-recombinant) with the very same characteristics as that claimed in the instant claims (see above). Using the purified enzyme taught by Uozumi et al. it would have been obvious to one of ordinary skill in the art to make the recombinant form of the same using the common knowledge of cloning available in the art of molecular biology. It is common knowledge in the art that recombinant proteins of a purified protein can be made by obtaining the amino acid sequence of a small portion of the purified protein followed by making oligonucleotide probes and synthesizing cDNA clones using a cDNA library. It is also common knowledge in the art that once a full length cDNA clone becomes available, it can be subcloned into expression vector followed by transforming a host cell. By culturing such transformed host cells under conditions ideal for expression of the heterologous polypeptide those skilled in the art can harvest and purify the

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recombinant protein. Several commercial kits are available in the art to perform such experiments including several commercial cDNA libraries of several experimental model animals such as mouse, rats, pigs and bovines. One of ordinary skill in the art would have been motivated to make a recombinant form of the above protein for either making the protein in larger amounts, or for studying the molecular structure of the enzyme or simply to study the enzyme kinetics in more detail. One of ordinary skill in the art would have a reasonable expectation of success since Uozumi et al. provide the purified protein and the art provides the techniques for making a recombinant form of the above protein.

Therefore, the above invention would have been *prima facie* obvious to one of ordinary skill in the art.

Conclusion

None of the claims are allowable.

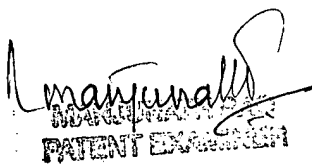
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 703-306-5681. The examiner can normally be reached on 7.30 a.m. to 4.00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0196.



Manjunath N. Rao
February 12, 2004